

REMARKS

Claims 1-21 were pending in this application before receipt of the Office Action dated June 27, 2003, Paper No. 7. With this Amendment, Applicants have added new claims 22-40. Therefore, claims 1-40 are now pending.

The amendment to claim 1, replacing the term "consisting of" with "comprising" in the preamble is supported by the disclosure in the specification of additional steps that can be added to the claimed process, for example, drying microparticles. See specification at 19, line 17 through page 20, line 2. Therefore, this amendment does not add new matter.

New claims 22-40 were derived from subject matter originally present in the claims they depend from, and therefore, do not add new matter.

Claim Objections

The Office objected to claims 1 and 2 because of the terms "chosen from" in these claims. Applicants have amended claims 1 and 2 to delete the term "chosen from" or "advantageously chosen from," but has not elected to use the term "selected from the group consisting of," as the Office suggested.

Applicants point out that "selected from the group consisting of" is not the only acceptable alternative language format. MPEP § 2173.05(h) states the proper test: "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims." The guidance for examination continues: "One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B and C.'" MPEP § 2173.05(h)(I), *citing Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925) (emphasis added). Other examples of acceptable alternative claim language

published by the PTO may be found in the following sources: MPEP Appendix AI (PCT), Example 20, p. AI-44 of the July 1998 edition ("wherein R1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S)."); *Training Materials For Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph - Enablement Chemical/Biotechnical Applications*, released August, 1996 ("X selected from A, B, and C"). In sum, the PTO expects and allows alternative claim language other than the strict formulation "selected from the group consisting of," and provides a test for determining proper alternative claim language.

Applying the proper test to Applicants' claim language, no uncertainty or ambiguity is found. For example, in claim 1 it is clear that the curing agent may be water, alcohols, or a mixture of water and alcohols. Applicants find "no uncertainty or ambiguity with respect to the question of scope or clarity" of this claim language.

Therefore, Applicants request that this objection be withdrawn.

Rejection under 35 U.S.C. § 102

The Office rejected claims 1-20 as being anticipated by WO 95/13799 under 35 U.S.C. § 102(b). In this rejection, the Office asserted that WO 95/13799 teaches a process for microencapsulating an active agent by coacervation, with features that are asserted to be similar to those of the claimed invention.

Applicants traverse this rejection because WO 95/13799 does not teach microencapsulation by *coacervation*, but instead teaches microencapsulation by *emulsification*. As indicated in the background to the invention in the specification, there are

[t]wo main types of microencapsulation . . .

-solvent-free techniques, for instance spray-congealing, extrusion (coextrusion/spheronization), gelation, prilling and precipitation of supercritical solutions (RESS), and

-solvent techniques, for instance nebulization, coacervation, emulsion-evaporation, emulsion-extraction, and variants thereof starting with water/oil/water double emulsions.

Page 2, lines 16-27. Therefore, coacervation is distinct from emulsion techniques.

The technique of emulsion includes two phases. A first phase is prepared, containing the active principle dissolved or dispersed in a solution of polymer in an organic solvent. The second phase contains a non-miscible dispersing solvent (non-solvent), and the first and second phases are combined. Then, under agitation, the organic solvent is evaporated and microspheres are isolated by filtration or centrifugation.

In contrast, the technique of coacervation uses an aggregation phenomenon. The active principle is dissolved or dispersed in a solution of polymer in an organic solvent. Then, coacervation is induced by addition of a non-solvent. Coacervation leads to the formation of two phases: 1) the coacervate, which is rich in polymer and poor in solvent; and 2) the supernatant, which is poor in polymer and rich in solvent. The droplets of coacervate gradually settle out from the surface of the active principle. Finally, a curing agent is added to allow the formation of a continuous polymer film around the active principle.

Claim 1 unambiguously recites a process for microencapsulating an active principle by coacervation, because, as recited, the polymer containing the active principle is "dissolved in an organic solvent" and coacervation is "induced by addition of a nonsolvent". Furthermore, the claimed process includes the "addition of a curing agent". Each of these elements is characteristic of coacervation, not of emulsion. In

contrast, WO 95/13799 does not teach or suggest a process for microencapsulating an active principle by coacervation, but instead teaches a process of emulsion.

Specifically, WO 95/13799 describes the invention disclosed as a process in which "the organic phase and the aqueous phase are pumped so that the two phases flow simultaneously through a static mixer, thereby forming an emulsion . . ." p. 22, line 30, through p. 23, line 1. These two phases are typical of emulsion, not coacervation. Because Applicants' claimed invention is not anticipated by WO 95/13799, Applicants respectfully request that the rejection be withdrawn.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 9, 2003

By: 

Deborah Katz

Reg. No. 51,863

Phone: (202) 408-4382

Fax: (202) 408-4400

E-mail: deborah.katz@finnegan.com

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com